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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,648

03/02/2004

James P. Elia

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3064

7590

10/23/2006

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,648	ELIA, JAMES P.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 159-223 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 159-223 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 159 (in part), 160-167, 188-191 (in part), 192-199, drawn to methods of treating arthritis comprising administering cells, classified in class 424, subclass 93.1.
- II. Claims 159 (in part), 168, 188-191 (in part), drawn to methods of treating arthritis comprising administering extracellular matrix, classified in class 424, subclass 484.
- III. Claims 159 (in part), 169, 188-191 (in part) , drawn to methods of treating arthritis comprising administering genes, classified in class 514, subclass 44.
- IV. Claims 159 (in part), 170-172 (in part), 188-191 (in part), 206-208 (in part), 209-211 (in part), drawn to methods of treating arthritis comprising administering cells and a physiological nutrient culture, classification dependent upon what is intended to constitute a physiological nutrient culture.
- V. Claims 159 (in part), 173-175 (in part), 188-191 (in part), 212-217 (in part), drawn to methods of treating arthritis comprising administering cells and a cell nutrient culture, classification dependent upon what is intended to constitute a cell nutrient culture.

- VI. Claims 159 (in part), 182-191 (in part), 218-223 (in part), drawn to methods of treating arthritis comprising administering cells and a physiological medium, classification dependent upon what is intended to constitute a physiological medium.
- VII. Claims 159 (in part), 170-172 (in part), 188-191 (in part), 206-211 (in part), drawn to methods of treating arthritis comprising administering extracellular matrix and a physiological nutrient culture, classification dependent upon what is intended to constitute a physiological nutrient culture.
- VIII. Claims 159 (in part), 173-175 (in part), 188-191 (in part), 212-217 (in part), drawn to methods of treating arthritis comprising administering extracellular matrix and a cell nutrient culture, classification dependent upon what is intended to constitute a cell nutrient culture.
- IX. Claims 159 (in part), 182-184 (in part), 188-191 (in part), 218-223 (in part), drawn to methods of treating arthritis comprising administering extracellular matrix and a physiological medium, classification dependent upon what is intended to constitute a physiological medium.
- X. Claims 159 (in part), 170-172 (in part), 188-191 (in part), 206-211 (in part), drawn to methods of treating arthritis comprising administering genes and a physiological nutrient culture, classification dependent upon what is intended to constitute a physiological nutrient culture.

- XI. Claims 159 (in part), 173-175 (in part), 188-191 (in part), 212-217 (in part), drawn to methods of treating arthritis comprising administering genes and a cell nutrient culture, classification dependent upon what is intended to constitute a cell nutrient culture.
- XII. Claims 159 (in part), 182-184 (in part), 188-191 (in part), 218-223 (in part), drawn to methods of treating arthritis comprising administering genes and a physiological medium, classification dependent upon what is intended to constitute a physiological medium.
- XIII. Claims 159 (in part), 188-191 (in part), 200-202, drawn to methods of treating arthritis comprising administering genes and cells, classified in class 514, subclass 44.
- XIV. Claims 159 (in part), 188-191 (in part), 203-205, drawn to methods of treating arthritis comprising administering proteins and cells, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XIV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed processes have materially different designs in that structurally different active agents are administered. Furthermore, the inventions as claimed do not

encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Each Group requires its own search.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ECK

Elizabeth C. Kemmerer

**ELIZABETH KEMMERER
PRIMARY EXAMINER**